

REMARKS

I. Status of the Claims

Claims 1-26 are pending in the application. Claims 6-26 stand withdrawn pursuant to a restriction requirement, and are hereby canceled. Thus, claims 1-5 are under examination and stand rejected, variously, under 35 U.S.C. §101, §112 (1st), §112 (2nd) and §102. The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

II. Formalities

The examiner has requested a sequence listing in compliance with 37 C.F.R. §1.821-1.825. A new Sequence Listing is attached.

The Abstract is objected to as containing more than 150 words. A revised Abstract is provided.

III. Rejection Under 35 U.S.C. §101

Claim 1 is rejected as reading on native EBV. Applicants have amended the claim to remove any reference to a whole virus.

IV. Rejection Under 35 U.S.C. §112, First Paragraph

Claims 1, 3 and 5 are rejected under the first paragraph of §112 as lacking an enabling disclosure. Applicants have amended claim 1 to recite a specific version of claim 2 (see support at pages 19-20 of the specification). Thus, applicants will address the rejection in the context of the revised claims.

First, the examiner argues that prevention or treatment of any autoimmune disorder is not supported. Applicants revised claims do not use this language.

Second, the claims now recite only those antigens (or nucleic acids encoding them) that lack or have altered an epitope that reacts with an autoimmune antibody (*i.e.*, an antibody that binds to an autoantigen).

Third, the examiner argues that only three particular peptides of claim 4 are enabled, but applicants submit that these peptides are supportive of the more generic recitations in claim 1 (“wherein epitopes of said EBV polypeptide reacting with antibody against an autoantigen are altered or deleted”), claim 2 (“the altered or deleted epitope is one that reacts with an anti-Sm antibody”), and claim 5 (“the altered or deleted epitope reacts with an anti-Sm B/B’ antibody”).

As such, it is believed that each of these claims is enabled, and that the rejection is overcome. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

V. Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 1-3 and 5 are rejected under the second paragraph of §112 as indefinite. First, the term “component” is deemed vague. Applicants traverse, but the claim has been amended to recite “polypeptide.” Second, the term “one or more structures” is objected to, but this language has been removed from the claims.

VI. Rejections Under 35 U.S.C. §102

A. Finerty or Morgan

Finerty *et al.* and Morgan *et al.* are cited as teaching a recombinant envelope glycoprotein (gp340) of EBV in a vaccine formulation. Applicants traverse. Neither reference apparently

teaches a *modified* EBV polypeptide where epitopes of the EBV polypeptide reacting with antibody against an autoantigen are altered or deleted. Reconsideration and withdrawal of the rejection is respectfully requested.

B. Milman

Milman *et al.* is cited as teaching a recombinant EBV1 nuclear protein 1 that is said to lack N- and C-terminal for use in a vaccine. Applicants traverse. To the extent that the reference teaches a modified EBV polypeptide, there is *no evidence of record* to indicate that epitopes of this EBV polypeptide reacting with antibody against an autoantigen are altered or deleted. Reconsideration and withdrawal of the rejection is respectfully requested.

C. Ambinder

Ambinder *et al.* is cited as teaching recombinant vectors/plasmids encoding several truncated EBV nuclear antigen 1. Applicants traverse. To the extent that the reference teaches a modified EBV polypeptide, there is *no evidence of record* to indicate that epitopes of this EBV polypeptide reacting with antibody against an autoantigen are altered or deleted. Reconsideration and withdrawal of the rejection is respectfully requested.

D. U.S. Patent 4,707,358

The '358 patent is cited as teaching immunogenic peptides in a pharmaceutical carrier, where the "peptide" is a surface antigen of EBV and is expressed recombinantly. Applicants traverse. The reference appears to teach EBV polypeptides of at least 2.8 kDa in length, which are not seen to be modified, and there is *no evidence of record* to indicate that epitopes of these

EBV polypeptides reacting with antibody against an autoantigen are altered or deleted. Reconsideration and withdrawal of the rejection is respectfully requested.

E. Rhodes

Rhodes *et al.* is cited as teaching a synthetic peptide with an adjuvant, where the peptide is derived from EBV nuclear antigen 1 and does not contain any of the sequences of claim 4. Applicants traverse. The reference does not teach a polypeptide, and the peptide does indeed contain an epitope (poly-GA) that reacts with antibody against an autoantigen. Reconsideration and withdrawal of the rejection is respectfully requested.

F. Finnerty or Gu

Finerty *et al.* and Gu *et al.* are cited as teaching a recombinant envelope glycoprotein (gp340) of EBV in a vaccine formulation. Applicants traverse. Neither reference apparently teaches a **modified** EBV polypeptide where epitopes of the EBV polypeptide reacting with antibody against an autoantigen are altered or deleted.

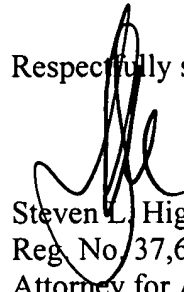
G. Gu

Gu *et al.* is cited as teaching a recombinant vaccinia virus expressing the EBV envelope glycoprotein (gp340) in a vaccine formulation. Applicants traverse. The reference apparently does not teach a **modified** EBV polypeptide where epitopes of the EBV polypeptide reacting with antibody against an autoantigen are altered or deleted.

VII. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. The examiner is invited to contact the undersigned attorney at (512) 536-3184 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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